UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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PROVEPHARM, INC.,

Plaintiff,

-against-

AKORN, INC.,

Defendant.
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ORDER
17-CV-7087(SJF)(AKT)

FEUERSTEIN, District Judge:

I. Introduction

On December 5, 2017, plaintiff Provepharm, Inc. ("plaintiff" or "Provepharm") commenced this action against defendant Akorn, Inc. ("defendant" or "Akorn"), seeking, *inter alia*, damages and injunctive relief for Akorn's allegedly false advertising of its methylene blue product in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and Section 350(e)(3) of the New York General Business Law; unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the common law; and deceptive trade practices in violation of Section 349(h) of the New York General Business Law.[1] Issue was joined by the service of an answer on behalf of Akorn on or about February 5, 2018. On August 27, 2018, Akorn served an amended answer, *inter alia*, asserting two (2) counterclaims against Provepharm seeking damages and injunctive relief for Provepharm's alleged monopolization and attempted monopolization of the methylene blue market in the United States in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. Pending before the Court, *inter alia*, are Provepharm's motion to dismiss Akorn's counterclaims in their entirety pursuant to Rule

[1] This case was originally assigned to the Honorable Arthur D. Spatt, United States District Judge. On October 3, 2018, Judge Spatt entered an order of recusal and the case was reassigned to the undersigned.

12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim for relief; and Akorn's motion pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure to amend its counterclaims. For the reasons set forth below, Provepharm's motion to dismiss is denied and Akorn's motion to amend is granted.

II. Background

A. Factual Allegations[2]

This case concerns the drug methylthioninium chloride, also known as methylene blue, (Counterclaim ["Countercl."], ¶ 8; Proposed Amended Counterclaims ["PAC"], ¶ 8), which was originally developed in the nineteenth (19th) century and has been used clinically as both a dye and a medication to treat a variety of conditions, including methemoglobinemia. (Complaint ["Compl."], ¶ 14; Amended Answer ["Am. Ans."], ¶ 14; *see also* Countercl., ¶ 8; PAC, ¶ 8). Methemoglobinemia is a rare and life-threatening disorder in which blood cells produce an abnormal amount of methemoglobin, which is a modified form of hemoglobin. (Compl., ¶ 12; Am. Ans., ¶ 12; *see also* Countercl., ¶ 8; PAC, ¶ 8). Since the hemoglobin in patients with methemoglobinemia cannot effectively release oxygen to body tissues, those tissues may be deprived of an adequate oxygen supply, leading to tissue hypoxia. (Compl., ¶ 13; Am. Ans., ¶ 13). Thus, patients with methemoglobinemia can experience cardiac, pulmonary, and neurological symptoms; and, in severe cases, death. (Compl., ¶ 13; Am. Ans., ¶ 13). Patients with acquired methemoglobinemia can be treated by delivering a solution of methylene blue intravenously, thereby restoring the iron in hemoglobin to its normal oxygen-carrying state. (Compl., ¶ 14; Am. Ans., ¶ 14; *see also* Countercl., ¶ 8; PAC, ¶ 8).

[2] The factual allegations in the counterclaims are assumed to be true for purposes of this motion and do not constitute findings of fact by the Court.

Although the only use for methylene blue that is approved by the United States Food and Drug Administration ("FDA") is for the treatment of methemoglobinemia, "today methylene blue is used by healthcare providers for a multitude of unapproved indications, for example as an antidote for cyanide poisoning, and is often a component in other medications." (Countercl., ¶ 8; PAC, ¶ 8).

On its website, Akorn describes itself as "a niche pharmaceutical company that develops, manufactures and markets generic and branded prescription pharmaceuticals as well as animal and consumer health products[,] . . . [which] specialize[s] in difficult-to-manufacture sterile and no-sterile dosage forms including: ophthalmics, injectables, oral liquids, optics, topicals, inhalants, and nasal sprays." (Compl., ¶ 33; Am. Ans., ¶ 33). Akorn originally began marketing methylene blue in 2009. (Compl., ¶ 34; Am. Ans., ¶ 34).

Provepharm is a competitor of Akorn in connection with the sale of methylene blue injection products in the United States. (Countercl., ¶ 4; PAC, ¶ 4).

Until 2016, all companies that manufactured and sold methylene blue did so under a "grandfather" status, which exempts pre-existing drugs meeting certain criteria from the requirements: (i) of having an approved New Drug Application ("NDA") under legislation enacted in 1938; and (ii) of proving effectiveness under legislation enacted in 1962. (Countercl., ¶¶ 9-11; PAC, ¶¶ 9-11). Akorn sold its methylene blue products in the United States under this "grandfather" status for decades. (Countercl., ¶¶ 11, 31; PAC, ¶¶ 11, 36).

Provepharm, whose parent companies are based in France, "developed a process to manufacture a purer form of methylene blue" that would comply with the stricter limitations for metal catalyst impurities adopted by European regulatory bodies, and "obtained several patents purportedly covering their manufacturing process for the purer form of methylene blue" (the

"Methylene Blue Patents"). (Countercl., ¶ 14; PAC, ¶ 14; *see also* Declaration of Kathy Grant ["Grant Decl."], Ex. 6-8[3]).

In 2011, Provepharm obtained approval from the European Medicines Agency to market its methylene blue product in Europe, (Countercl., ¶ 15; PAC, ¶ 16); and sought to obtain FDA approval of an NDA to market a "drug product in which methylene blue is the active pharmaceutical ingredient ('API')" under Section 505(b)(2) of the Food, Drug, and Cosmetic Act ("FDCA"). (Countercl., ¶¶ 16-17; PAC, ¶¶ 16-18). Provepharm ultimately obtained FDA approval for its drug product, ProvayBlue® methylene blue injection USP ("ProvayBlue®"), on April 8, 2016. (Compl., ¶ 1; Am. Ans., ¶ 1; Countercl., ¶ 17; PAC, ¶ 18). According to Akorn, "[a]fter Provepharm obtained approval for ProvayBlue®, Akorn and others cannot market methylene blue in the United States unless they file and obtain approval of their own NDA or otherwise received exemptions from such requirements from FDA." (Countercl., ¶ 31; PAC, ¶ 36).

In approving Provepharm's NDA, the FDA also awarded ProvayBlue® Orphan Drug Exclusivity ("ODE")[4] for the treatment of pediatric and adult patients with acquired methemoglobinemia. (Countercl., ¶¶ 19, 21; PAC, ¶¶ 20, 22). ODE runs for a period of seven (7) years, during which the FDA "will not approve any other NDAs for the same API for the same condition." (Countercl., ¶ 19; PAC, ¶ 20). However, the FDA may "approve other NDAs for the same API if they are directed to other conditions and do not include the orphan condition."

[3] Since the counterclaims and proposed amended counterclaims specifically refer to United States Patent Nos. 9,227,945, dated January 5, 2016; 8,765,942, dated July 1, 2014; and 8,815,850, dated August 26, 2014, (Countercl., ¶ 14; PAC, ¶ 14), those exhibits are properly considered on this motion, as set forth below.

[4] According to Akorn, "ODE is available to new drug products for which the approved indication is a disease or condition affecting fewer than 200,000 people in the United States, or if greater than 200,000 people, then there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States." (Countercl., ¶ 19; PAC, ¶ 20).

(Countercl., ¶ 19; PAC, ¶ 20). Thus, although the FDA "cannot approve any other NDAs for the use of methylene blue to treat pediatric and adult patients with acquired methemoglobinemia until April 8, 2023[,] . . . [it can] approve other NDAs for the use of methylene blue for any other indication. . . ." (Countercl., ¶¶ 21, 32; PAC, ¶¶ 22, 37).

However, according to Akorn, "[w]hile Provepharm was obtaining approval from the FDA for ProvayBlue®, it was also soliciting the United States Pharmacopeia ('USP') to revise the official monograph for the API classified as methylene blue" in order to "foreclose any others from pursuing NDAs for the use of methylene blue for other indications."[5] (Countercl., ¶ 22; PAC, ¶ 23). Specifically, "[o]n or about May 24, 2013, Provepharm requested that USP revise the criteria for methylene blue API and methylene blue injection, *i.e.*, a sterile solution of methylene blue in water for injection, to include the pentahydrate form of methylene blue—a different hydrate form of methylene blue that purportedly results from Provepharm's manufacturing process—and to change the standardized assay for other hydrate forms." (Countercl., ¶ 22; PAC, ¶ 23; Grant Decl., Ex. 17[6]).

"As a public standards-setting organization, the USP has an express policy of impartiality and of not favoring one manufacturer over another in setting its standards." (Countercl., ¶ 25;

[5] According to Akorn, the USP "is a scientific nonprofit organization that sets standards for identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements that are manufactured, distributed and consumed worldwide[,] . . . [which] are enforceable in the United States by the FDA . . . [and] are recognized and required under federal law." (Countercl., ¶ 23; PAC, ¶ 24). "When such medicines comply with the USP-NF [United States Pharmacopeia and National Formulary] standards, the products may be marketed and labelled as USP-compliant, generally by including 'USP' after the product name." (Countercl., ¶ 24; PAC, ¶ 25). According to Akorn, "[t]hat was how [its] methylene products were labeled because they complied at all times with the then-current USP-NF until Provepharm instigated the November 2016 changes." (PAC, ¶ 25).

[6] Since the counterclaims and proposed amended counterclaims specifically refer to the documents included in plaintiff's Exhibit 17, (Countercl., ¶ 22; PAC, ¶ 23), those documents are properly considered on this motion, as set forth below.

PAC, ¶ 26; Grant Decl., Ex. 4-5[7]). According to Akorn, in order "[t]o ensure impartiality and its policy of not favoring any one manufacturer over another, and 'because USP's standards are intended to be public standards available for the use and benefit of all parties, USP requests that sponsors disclose in their Requests for Revision whether any portion of the methods or procedures submitted is subject to patent or other sponsor-held intellectual property rights.'" (Countercl., ¶ 25; PAC, ¶ 27) (quoting Submissions Guideline at Grant Decl., Ex. 4).

Akorn alleges that Provepharm: (i) "violated clear USP rules and policies when it concealed the fact that [it] owned patents for the manufacturing process necessary to produce methylene blue in the form that [it] urged USP to adopt as [the] standard for methylene blue[,]"[8] (Countercl., ¶ 28; PAC, ¶ 29); (ii) "falsely asserted that the FDA required the inclusion of Provepharm's proposed methods and specifications[,]" (Countercl., ¶ 29; PAC, ¶ 34); and (iii) "failed to inform USP that the proposed methods and specifications 'required' by the FDA were

[7] Since the counterclaims and proposed amended counterclaims specifically refer to the "USP Guideline for Submitting Requests for Revision to USP-NF, General Information for All Submissions" ("Submissions Guideline"), and the USP Code of Ethics, (Countercl., ¶ 25; PAC, ¶ 26), those documents are properly considered on this motion, as set forth below.

[8] In its proposed amended counterclaims, Akorn additionally alleges, *inter alia*, (i) that Provepharm's June 30, 2014 submission to USP, which "is a 151-page document in which the following sentence appears: 'Methylene Blue drug substance is manufactured by Provepharm manufacturers using the patented method licensed by the Applicant[,]'" (the "Patented Method Statement"), (PAC, ¶ 30; *see* Grant Decl., Ex. 1 at 2992), did not disclose the existence of the Methylene Blue Patents to USP because (A) "[t]he first of the Methylene Blue Patents did not issue until July 1, 2014," and, thus, did not exist at the time of the June 30, 2014 submission, and (B) "there was no license between Provepharm and any manufacturer of the methylene blue drug substance for the Methylene Blue Patents[,]" and, thus, the Patented Method Statement was false[,]" (PAC, ¶ 31); (ii) that the USP "did not, in fact, appreciate" the Patented Method Statement as a disclosure of the Methylene Blue Patents because (A) the Patented Method Statement "did not identify any specific patents or patent applications[,] . . . did not have enough information for USP to understand the situation with respect to the Methylene Blue Patents[,] . . . [and] was insufficient for USP to understand that the Methylene Blue Patents existed or their relevance to the proposed monograph revision[,]" and (B) "USP did not even notice the Patented Method Statement[,]" (*id.*, ¶ 32); (iii) that "[i]f USP had noticed the Patented Method Statement, and if the Patented Method Statement contained sufficient information for USP to understand the existence of the Methylene Blue Patents and their relevant [sic] to the proposed monograph revision, USP would have taken action to prevent the Methylene Blue Patents from affecting anyone's ability to use or meet a proposed revised monograph," including (A) requiring Provepharm to either abandon the Methylene Blue Patents or license them royalty-free, or, (B) if Provepharm refused, modifying the proposed monograph "so that the Methylene Blue Patents would not affect anyone's ability to use or meet a proposed revised monograph[,]" (*id.*, ¶ 33); and (iv) that "[b]ut for Provepharm's failure to disclose the Methylene Blue Patents to USP, the ability of anyone, including Akorn, to use or meet the proposed revised monograph would not be affected by the Methylene Blue Patents." (*Id.*).

originally proposed by Provepharm[] . . . [and] that in order to meet the 'required,' proposed specifications using the proposed methods, a company would necessarily need to manufacture methylene blue API using manufacturing processes allegedly covered by [Provepharm's Methylene Blue Patents]." (Countercl., ¶ 29; PAC, ¶ 34).

On July 29, 2016, "USP posted revisions for the methylene blue monographs, which required Provepharm's proposed specifications and assay testing method, and later adopted the revised monographs[,]" as a result of which "no other drug manufacturer can file an NDA having methylene blue API without producing the API in accordance with manufacturing processes allegedly covered by [Provepharm's Methylene Blue Patents]." (Countercl., ¶ 30; PAC, ¶ 35; *see also* Countercl., ¶ 32; PAC, ¶ 35). Akorn alleges that "as a result of Provepharm successfully petitioning the USP to revise the monographs for methylene blue and methylene blue injection, Akorn and others cannot submit their own NDAs for approval to market methylene blue without risking being the subject of suits for patent infringement." (Countercl., ¶ 32; PAC, ¶ 37).

According to Akorn, "[t]he net result of Provepharm's two-pronged attack," (Countercl., ¶ 31; PAC, ¶ 36), *i.e.*, obtaining FDA approval of ProvayBlue® with ODE for the treatment of pediatric and adult patients with acquired methemoglobinemia, as well as revision of the USP official monographs for methylene blue, "was the effective monopolization of the market for methylene blue in the United States." (Countercl., ¶ 31; PAC, ¶ 36). Akorn alleges that it "was forced to exit the market for its methylene blue in October of 2016, as they no longer conformed with the revised USP monograph, leaving Provepharm as the sole source of methylene blue in the United States and thus holding a monopoly in the relevant market[,]" (Countercl., ¶ 33; PAC, ¶ 38); and, alternatively, that "Provepharm obtained a dangerous probability of monopolizing the relevant market." (Countercl., ¶ 33; PAC, ¶ 38).

Akorn alleges that as a result of the change instigated to the methylene blue USP by Provepharm, its methylene blue product was removed from the market "earlier than what would have occurred had Provepharm only obtained an approved NDA[,]" (Countercl., ¶ 34; PAC, ¶ 39), because although its "grandfather" status would typically have allowed it to continue to sell its methylene blue products during a six (6)- to twelve (12)-month "transition period" after the FDA approved Provepharm's NDA, it could no longer use "the original [USP] standard to which its grandfathered methylene products conformed" and, thus, "could not manufacture and sell additional units of methylene products." (Countercl., ¶¶ 34-36; PAC, ¶¶ 39-41). According to Akorn, "[i]t was forced to exit the market in October of 2016 and remained so until June 2017, when the FDA permitted [it] to temporarily manufacture methylene blue using the expired USP standard[;]" and Provepharm "achieved actual monopolization in fact" during that approximately eight (8)-month period. (Countercl., ¶ 36; PAC, ¶ 41).

Akorn further alleges that the FDA has temporarily permitted it "to resume manufacturing and selling methylene blue products qualified against the expired original standard, . . . and [it] has re-entered the market, but at a substantially reduced market share that is artificially lower than would have occurred had Provepharm not instigated the change to the USP monographs." (Countercl., ¶¶ 37-38; PAC, ¶¶ 42-43). Akorn further alleges that in the process of its temporary re-entry into the market, it has "exhausted its supply of the expired original standard[,]" (Countercl., ¶ 38; PAC, ¶ 43); and that "[a]s a result of Provepharm instigating the change to the USP monographs, additional quantities of the expired original standard are no longer available" and it "cannot manufacture additional methylene blue products[,]" even if the FDA continues to request it to do so. (Countercl., ¶ 38; PAC, ¶ 43). According to Akorn, once it "exhausts its on-hand supply of methylene blue products, it will once again be forced from the

market, and Provepharm will have once again achieved monopolization of the methylene blue market." (Countercl., ¶ 38; PAC, ¶ 43).

B. Procedural History

On December 5, 2017, Provepharm commenced this action against Akorn seeking, *inter alia*, damages and injunctive relief for Akorn's allegedly false advertising of its methylene blue product in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and Section 350(e)(3) of the New York General Business Law (Counts I and V, respectively); unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the common law (Counts II and III, respectively); and deceptive trade practices in violation of Section 349(h) of the New York General Business Law (Count IV). Issue was joined by the service of an answer on behalf of Akorn on or about February 5, 2018.

Following a pre-motion conference before Judge Spatt on May 29, 2018, the parties filed a joint letter regarding their negotiated discovery schedule, which, *inter alia*, set August 27, 2018 as the "[f]inal date to amend the pleadings." (Docket Entry ["DE"] 32). On August 27, 2018, Akorn served an amended answer, *inter alia*, asserting two (2) counterclaims against Provepharm seeking damages and injunctive relief for Provepharm's alleged monopolization and attempted monopolization of the methylene blue market in the United States in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2. With respect to its first counterclaim for actual monopolization, Akorn alleges, *inter alia*, that Provepharm's anticompetitive conduct excluded it from the methylene blue market in the United States, as a result of which it "was unable to sell methylene blue products for several months, and even on its return to the methylene blue market, has suffered diminished sales of methylene blue products, resulting in substantial damages."

(Countercl., ¶¶ 41-42; PAC, ¶¶ 46-47). With respect to its second counterclaim for attempted monopolization, Akorn alleges, *inter alia*, (i) that Provepharm, through "anticompetitive and exclusionary acts," "achieved a dangerous probability of success of monopolizing the relevant market[,] . . . [and] will maintain monopoly over the methylene blue injection USP in the United States[,]" (Countercl., ¶ 47; PAC, ¶ 52); and (ii) that "[a]s a result of being blocked from selling methylene blue, Akorn will suffer antitrust injury."[9] (Countercl., ¶ 47; PAC, ¶ 52).

Provepharm now moves pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss Akorn's counterclaims against it in their entirety for failure to state a claim for relief; and Akorn moves pursuant to Rule 15(a) of the Federal Rules of Civil Procedure to amend its counterclaims to "include additional allegations based on newly-discovered evidence and testimony[;] . . . provide further factual support for [its] counterclaims[;] . . . [and] rebut the factual arguments that Provepharm made in its motion to dismiss." (Akorn's Memorandum of Law on Motion for Leave to Amend its Counterclaims ["Akorn Mem."] at 5).

III. Discussion

A. Motion to Amend

Initially, the branch of Provepharm's motion seeking dismissal of the counterclaims based upon Akorn's purported failure to comply with Fed. R. Civ. P. 15(a)(2) is denied. Where, as here, a defendant files an amended answer that includes a counterclaim without seeking court

[9] In its proposed amended counterclaims, Akorn also alleges with respect to its second counterclaim for attempted monopolization that Provepharm "had a specific intent to monopolize the relevant market[,] . . . [and] purposefully acted to wrongfully block anyone else, including specifically Akorn, from selling methylene blue in the United States[,] . . . [because] although FDA granted seven years of exclusivity to Provepharm for the very limited use of treating acquired methemoglobinemia, Provepharm's actions with USP to revise the methylene blue monographs will prevent Akorn and others from filing NDAs for any other indications of use, including for example the numerous 'off label' uses for which Akorn's methylene blue products and Provepharm's ProvayBlue® product are purchased." (PAC, ¶ 51).

permission under Rule 15(a)(2) of the Federal Rules of Civil Procedure, the plaintiff-counterdefendant may challenge the counterclaim in several ways: "(1) by a Rule 12(b)(6) motion if relevant undisputed facts appear on the face of the pleadings or in the record, (2) by a Rule 56 motion if relevant undisputed facts can be presented by affidavit, or (3) by an answer under Rule 8(c) if relevant facts are in dispute." *GEOMC Co., Ltd. v. Calmare Therapeutics Inc.*, 918 F.3d 92, 101 (2d Cir. 2019). "In ruling on a motion to dismiss a new counterclaim, a district court can either assess the new counterclaim's legal sufficiency or exercise the discretion the court would have been entitled to use if the counterclaimant had moved under Rule 15 to file the new counterclaim." *Id.*

"Leave to amend should be 'freely give[n] ... when justice so requires,' Fed. R. Civ. P. 15(a)(2), but 'should generally be denied in instances of futility, undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, or undue prejudice to the non-moving party[.]'" *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 28 (2d Cir. 2016) (alterations in original) (quoting *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d 122, 126 (2d Cir. 2008)). "A proposed amendment to a complaint is futile when it could not withstand a motion to dismiss." *F5 Capital v. Pappas*, 856 F.3d 61, 89 (2d Cir. 2017), *cert. denied*, 138 S. Ct. 473, 199 L. Ed. 2d 358 (2017) (quotations and citation omitted).

Where, as here, a party seeks to amend its pleading while a motion to dismiss is pending, "the Court has a variety of ways in which it may deal with the pending motion to dismiss, from denying the motion as moot to considering the merits of the motion in light of the amended [pleading]." *Kilpakis v. JPMorgan Chase Fin. Co., LLC*, 229 F. Supp. 3d 133, 139 (E.D.N.Y. 2017). Where, as here, "the proposed amended [pleading] does not seek to add new claims or parties, and the [opposing party] ha[s] had a sufficient opportunity to respond to the new

pleading, then, for the purposes of procedural efficiency, the merits of the pending motion to dismiss ought to be considered in light of the proposed amended [pleading]." *Id*. Accordingly, the Court considers the merits of Provepharm's motion to dismiss as if it were directed at Akorn's proposed amended counterclaims to determine whether the proposed amendments are futile.[10]

B. Sufficiency of Claims

1. Standard of Review

The standard of review on a motion made pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure is that a party plead sufficient facts "to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009). The plausibility standard requires "more than a sheer possibility that a defendant has acted unlawfully." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-- but it has not 'show[n]'-- 'that the pleader is entitled to relief.'" *Id.* at 679, 129 S. Ct. 1937 (brackets in original) (quoting Fed. R. Civ. P. 8(a)(2)). "Determining whether a [pleading] states a plausible claim for relief will[] . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.*

[10] Indeed, with the exception of the allegations pertaining to the Patented Method Selection and Provepharm's purported specific intent, Akorn's proposed amended counterclaims are virtually identical to its original counterclaims.

"A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Iqbal*, 556 U.S. at 678, 129 S. Ct. 1937 (quoting *Twombly*, 550 U.S. at 555, 127 S. Ct. 1955). "Nor does a [pleading] suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 557, 127 S. Ct. 1955). "Factual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the [pleading] are true (even if doubtful in fact)." *Twombly*, 550 U.S. at 555-56, 127 S. Ct. 1955 (citations omitted).

In deciding a motion pursuant to Rule 12(b)(6), the Court must liberally construe the claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences in favor of the pleader. *See Kim v. Kimm*, 884 F.3d 98, 102-03 (2d Cir. 2018); *Elias v. Rolling Stone LLC*, 872 F.3d 97, 104 (2d Cir. 2017). However, this tenet "is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678, 129 S. Ct. 1937. "While legal conclusions can provide the framework of a [pleading], they must be supported by factual allegations." *Id.* at 679, 129 S. Ct. 1937. "In keeping with these principles a court considering a motion to dismiss can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Id.*; *see also Ruston v. Town Bd. for Town of Skaneateles*, 610 F.3d 55, 59 (2d Cir. 2010).

Nonetheless, a party is not required to plead "specific evidence or extra facts beyond what is needed to make the claim plausible." *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120-21 (2d Cir. 2010); *accord Pension Benefit Guar. Corp. ex rel. St. Vincent Catholic Med. Ctrs. Ret. Plan v. Morgan Stanley Inv. Mgmt. Inc.*, 712 F.3d 705, 729-30 (2d Cir. 2013). "When there are well-pleaded factual allegations, a court should assume their veracity and then determine

whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679, 129 S. Ct. 1937.

In deciding a motion pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Court must limit itself to the facts alleged in the pleading, which are accepted as true; to any documents attached to the pleading as exhibits or incorporated by reference therein; to matters of which judicial notice may be taken; or to documents upon the terms and effect of which the pleading "relies heavily" and which are, thus, rendered "integral" thereto. *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 152-53 (2d Cir. 2002); *see also Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 230-31 (2d Cir. 2016). "A necessary prerequisite for taking into account materials extraneous to the complaint is that the plaintiff *rely* on the terms and effect of the document in drafting the complaint; mere notice or possession is not enough." *Nicosia*, 834 F.3d at 231 (emphasis in original) (quotations and citations omitted); *see also Goel v. Bunge, Ltd.*, 820 F.3d 554, 559 (2d Cir. 2016) ("Merely mentioning a document in the complaint will not satisfy th[e] [integral to the complaint] standard; indeed, even offering limited quotations from the document is not enough." (quotations and citation omitted)). "This generally occurs when the material considered is a contract or other legal document containing obligations upon which the plaintiff's complaint stands or falls, but which for some reason—usually because the document, read in its entirety, would undermine the legitimacy of the plaintiff's claim—was not attached to the complaint." *Nicosia*, 834 F.3d at 231(quotations and citation omitted); *accord Goel*, 820 F.3d at 559. Moreover, "even if a document is 'integral' to the complaint, it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document[,] . . . [and] that there exist no material disputed issues of fact regarding the relevance of the document."

Faulkner v. Beer, 463 F.3d 130, 134 (2d Cir. 2006) (citations omitted); *accord Nicosia*, 834 F.3d at 231.

Other than Provepharm's patents, (Grant Decl., Ex. 6-8); the USP Code of Ethics and Submissions Guideline, (*id.*, Ex. 4 & 5); Provepharm's submission to the USP dated June 30, 2014, including the Patented Method Statement, (*id.*, Ex. 1); and the documents submitted as Exhibit 17 to the declaration of Kathy Grant, all of which are specifically incorporated by reference in the proposed amended counterclaims, (*see* PAC, ¶¶ 14, 23, 26 and 30-33), the other extrinsic evidence submitted by Provepharm is not properly considered on this motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure because, *inter alia*, (i) none of it is attached to, or incorporated by reference in, the pleadings, nor does it contain matters on which judicial notice may properly be taken; and (ii) the counterclaims do not rely heavily upon the terms and effect of any of those documents such that they may properly be deemed as integral thereto, nor is it clear from the record that the documents are indisputably authentic or accurate. *See Chambers*, 282 F.3d at 152-53. Accordingly, pursuant to Rule 12(d) of the Federal Rules of Civil Procedure, the Court excludes all such extrinsic evidence, and the arguments based thereupon, from its consideration of this motion, and considers only the factual allegations in the complaint to which there is no dispute; the factual allegations in the counterclaims, which are assumed to be true for purposes of this motion only; and the seven (7) aforementioned exhibits that are incorporated by reference in the proposed amended counterclaims.

2. Section 2 of the Sherman Act

"Section 2 of the Sherman Act makes it an offense to 'monopolize, or attempt to monopolize ... any part of the trade or commerce among the several States.'" *New York ex rel.*

Schneiderman v. Actavis PLC, 787 F.3d 638, 651 (2d Cir. 2015) (quoting 15 U.S.C. § 2). As explained by the Supreme Court,

> "The purpose of the [Sherman] Act is not to protect businesses from the working of the market; it is to protect the public from the failure of the market. The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself. It does so not out of solicitude for private concerns but out of concern for the public interest. . . . Thus, this Court and other courts have been careful to avoid constructions of § 2 which might chill competition, rather than foster it."

Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 458, 113 S. Ct. 884, 122 L. Ed. 2d 247 (1993) (citations omitted). Accordingly, the conduct of a single firm, governed by § 2 of the Sherman Act, is "unlawful only when it actually monopolizes or dangerously threatens to do so." *Id.* at 459, 113 S. Ct. 884.

However, "there is no heightened pleading standard in antitrust cases[,]" *Wacker v. JP Morgan Chase & Co*, 678 F. App'x 27, 29 (2d Cir. Feb. 1, 2017) (summary order) (quoting *Concord Assocs., L.P. v. Entm't Props. Trust*, 817 F.3d 46, 52 (2d Cir. 2016)); and on a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the pleader "need only 'raise a reasonable expectation that discovery will reveal evidence of illegality.'" *Id.* (quoting *Mayor & City Council of Baltimore, Md. v. Citigroup Inc.*, 709 F.3d 129, 135 (2d Cir. 2013)).

"To establish monopolization in violation of § 2, a plaintiff must prove not only that the defendant possessed monopoly power in the relevant market, but that it willfully acquired or maintained that power 'as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" *Actavis*, 787 F.3d at 651 (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407, 124 S. Ct. 872, 157 L. Ed. 2d 823 (2004)); *accord Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d

485, 495 (2d Cir. 2004). In order to "demonstrate attempted monopolization a plaintiff must prove (1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Spectrum Sports*, 506 U.S. at 456, 113 S. Ct. 884. Thus, unlike actual monopolization, attempted monopolization "requires a finding of specific intent."[11] *Actavis*, 787 F.3d at 651; *see also Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602, 105 S. Ct. 2847, 86 L. Ed. 2d 467 (1985) (holding that an attempted monopolization claim requires proof of "a 'specific intent' to accomplish the forbidden objective," *i.e.*, "an intent which goes beyond the mere intent to do the act[,]" whereas on a claim for actual monopolization, "evidence of intent is merely relevant to the question whether the challenged conduct is fairly characterized as 'exclusionary' or 'anticompetitive' . . . or 'predatory.' (quotations and citations omitted)); *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 101 (2d Cir. 1998) ("Although the completed offense of monopolization requires only a general intent, a specific intent to destroy competition or build monopoly is essential to guilt for the mere attempt." (quotations and citation omitted)).

The latter element of an attempted monopolization claim, *i.e.*, a dangerous probability of actual monopolization, generally requires: (i) a definition of the relevant product and geographic market and examination of the defendant's market power, *Spectrum Sports*, 506 U.S. at 455, 459, 113 S. Ct. 884, *i.e.*, "the defendant's ability to lessen or destroy competition in that market[,]" *id.* at 456, 113 S. Ct. 884; and (ii) a showing of "more than intent alone." *Id.* at 457-58, 113 S. Ct. 884. Thus, "proof of unfair or predatory conduct alone is [not] sufficient to make out the offense of attempted monopolization." *Id.* at 457, 113 S. Ct. 884. A defendant "may not be liable for attempted monopolization under § 2 of the Sherman Act absent proof of a dangerous probability

[11] Since Provepharm does not challenge the sufficiency of the specific intent element in its motion to dismiss, it is not addressed herein.

that they would monopolize a particular market and specific intent to monopolize." *Id.* at 459, 113 S. Ct. 884.

a. Monopoly Power

"Monopoly power is 'the power to control prices or exclude competition[,]'" *Geneva*, 386 F.3d at 500 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391, 76 S. Ct. 994, 100 L. Ed. 2d 1264 (1956)), which "can be proven directly through evidence of control over prices or the exclusion of competition, or . . . inferred from a firm's large percentage share of the relevant market." *Id.*; *see also PepsiCo., Inc. v. Coca-Cola Co.*, 315 F.3d 101, 108 (2d Cir. 2002) ("The pertinent inquiry in a monopolization claim . . . is whether the defendant has engaged in improper conduct that has or is likely to have the effect of controlling prices or excluding competition, thus creating or maintaining market power. In the absence of [such] direct measurements of a defendant's ability to control prices or exclude competition, however, market power necessarily must be determined by reference to the area of effective competition—which, in turn, is determined by reference to a specific, defined product market. . . . Once a relevant market is determined, the defendant's share in that market can be used as a proxy for market power." (quotations and citations omitted)). "Once the relevant market is determined, [courts] consider a variety of factors in addition to the defendant's market share, including the strength of competition, barriers to entry, and the probable development of the market, . . . in order to determine whether there is a dangerous probability that, left unchecked, the defendant will attain monopoly power, *i.e.*, the ability (1) to price substantially above the competitive level and (2) to persist in doing so for a significant period without erosion by new entry or expansion." *AD/SAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 226–27 (2d Cir. 1999)

(quotations and citation omitted); *see also Tops Mkts.*, 142 F.3d at 100 ("In considering the likelihood of achieving monopoly power, we . . . consider[] the defendant's relevant market share in light of other market characteristics, including barriers to entry[,]" as well as strength of the competition, the probable development of the industry, the nature of the anticompetitive conduct and the elasticity of consumer demand). "[A] lesser degree of market power may establish an attempted monopolization claim than that necessary to establish a completed [or actual] monopolization claim." *Tops Mkts.*, 142 F.3d at 100.

However, "[t]o safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Verizon*, 540 U.S. at 407, 124 S. Ct. 872 (emphasis in original); *see also Actavis*, 787 F.3d at 652 ("Product innovation generally benefits consumers and inflicts harm on competitors, so courts look for evidence of exclusionary or anticompetitive effects in order to distinguish between conduct that defeats a competitor because of efficiency and consumer satisfaction and conduct that impedes competition through means other than competition on the merits." (quotations and citations omitted)). "Anticompetitive conduct is conduct without a legitimate business purpose that makes sense only because it eliminates competition." *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (quotations, alterations and citation omitted). "Conduct may be characterized as exclusionary if it does not further competition on the merits or does so in an unnecessarily restrictive way." *Merced Irrigation Dist. v. Barclays Bank PLC*, 165 F. Supp. 3d 122, 142 (S.D.N.Y. 2016) (quotations and citation omitted); *see also Aspen Skiing*, 472 U.S. at 605 n. 32, 105 S. Ct. 2847 ("'[E]xclusionary' comprehends at the most behavior that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." (quotations and citation omitted)). In order

to prove that the alleged monopolist 'willfully acquired or maintained its power, thereby causing unreasonable exclusionary or anticompetitive effects[,]'" *Wacker*, 678 F. App'x at 29 (quoting *Trans Sport, Inc. v. Starter Sportswear, Inc.*, 964 F.2d 186, 188 (2d Cir. 1992)), the claimant must "plead antitrust injury, *i.e.*, an 'injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *Wacker*, 678 F. App'x at 29 (quoting *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334, 110 S. Ct. 1884, 109 L. Ed. 2d 333 (1990)); *see also IQ Dental Supply, Inc. v. Henry Schein, Inc.*, 924 F.3d 57, 62 (2d Cir. May 10, 2019) ("A plaintiff raising an antitrust claim must demonstrate antitrust injury to ensure that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place." (quotations, alterations and citation omitted)).

i. Anticompetitive Conduct

In this Circuit, the bar for showing that a party has engaged in unlawful anticompetitive conduct "is a low one." *IQ Dental*, 924 F.3d at 63. Although "product improvement alone is [not] anticompetitive[,]" *Actavis*, 787 F.3d at 653-54, when such conduct is combined "with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, . . . and to impede competition, . . . [the] actions are anticompetitive under the Sherman Act." *Id.* at 654 (citations omitted).

There is no dispute that the relevant market in this case is the methylene blue market in the United States. The counterclaims and proposed amended counterclaims allege sufficient facts from which it may reasonably be inferred, *inter alia*, (i) that Provepharm possesses monopoly power, *i.e.*, the power to exclude competition, in the relevant market, or at least did so for the approximately eight (8)-month period from when the USP revised the monographs in accordance

with Provepharm's request until the FDA requested that Akorn temporarily re-enter the market to manufacture and sell methylene blue products qualified against the expired original standard;[12] and (ii) that Provepharm "willfully sought to maintain or attempted to maintain that monopoly in violation of § 2[,]" *Actavis*, 787 F.3d at 652, by, *inter alia*, combining its alleged improvement of its methylene blue product, for which it sought and obtained FDA approval, with its allegedly anticompetitive conduct, *i.e.*, its solicitation of the USP to revise the official monograph for methylene blue to include the pentahydrate form, while failing to disclose its patent rights on the manufacturing process allegedly necessary to produce that hydrate form of methylene blue, and to change the standardized assay for other hydrate forms, in order to significantly heighten barriers to entry and substantially foreclose competition in the methylene blue market in the United States. *See generally Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308, 314 (3d Cir. 2007)[13] ("[C]onduct that undermines the procompetitive benefits of private standard setting may, at least in some circumstances, be deemed anticompetitive under antitrust law. . . . We hold that (1) in a consensus-oriented private standard-setting environment, (2) a patent holder's intentionally false promise . . . [to a standard-determining organization

[12] Provepharm's assertion that "[t]he FDA's approval of ProvayBlue® led the USP to update and revise the monograph for methylene blue to mirror the FDA's approved standards for this injectable drug[,]" (Plaintiff's Reply Memorandum of Law in Further Support of its Motion to Dismiss ["Plf. Reply"] at 2), appears to be contradicted by the documents incorporated by reference in the counterclaims that are attached as exhibit 17 to the declaration of Kathy Grant. Those documents indicate, in relevant part, (i) that Provepharm commenced the process of seeking revision of the methylene blue monograph on or before May 24, 2013, *i.e.*, approximately three (3) years before it obtained FDA approval of its NDA, because the existing monograph was "old," did not "take into account the recent knowledge on the [different] hydrate forms of the Methylene Blue," and "describe[d] the Methylene Blue as trihydrate only[;]" (ii) that since Provepharm's API "contains mainly the pentahydrate form, which is the most stable form[,] . . . it doesn't strictly conform to the USP monograph;" and (iii) that Provepharm's objective in seeking revision of the monograph was "to have a product compliant with USP" and, thus, it was "look[ing] for the most efficient process to update the monograph in the meantime of the review of [its] NDA." (Grant Decl., Ex. 17 at 628).

[13] The plaintiff in *Broadcom* alleged that the defendant monopolized a market by "by falsely promising to license its patents according to the fair, reasonable, and non-discriminatory ('FRAND') terms set by the European Telecommunications Standards Institute ('ETSI') and its standards-defining organizations ('SDO') counterparts in the United States, but then reneging on those promises after it succeeded in having its technology included in the standard." 501 F.3d at 306.

('SDO')], (3) coupled with [the] SDO's reliance on that [misrepresentation] when including the technology in a standard, and (4) the patent holder's subsequent breach of that promise, is actionable anticompetitive conduct. . . . Deception in a consensus-driven private standard-setting environment harms the competitive process by obscuring the costs of including proprietary technology in a standard and increasing the likelihood that patent rights will confer monopoly power on the patent holder. . . ." (quotations and citations omitted)); *e.g. Amphastar Pharm., Inc. v. Momenta Pharm., Inc.*, 297 F. Supp. 3d 222, 230 (D. Mass. 2018) ("Intentional misrepresentations designed to deceive a standard-setting organization can constitute an antitrust violation. . . . By incorporating patented technology into a standard, the patent-holder obtains market power because adoption of the standard eliminates alternatives to the patented technology.")[14]

It may also reasonably be inferred from the factual allegations in Akorn's counterclaims and proposed amended counterclaims, including, *inter alia*, Provepharm's substantial share in the relevant market following the USP's revision of the methylene blue monograph, even following Akorn's limited re-entry into the market at the request of the FDA; the weakness of its competition; and the barriers to entry or re-entry into the market imposed by the revisions to the USP monograph, combined with the OED restrictions, that there is a dangerous probability that Provepharm will attain monopoly power in the methylene blue market in the United States sufficient to state a plausible claim for attempted monopolization under Section 2 of the Sherman Act.

[14] In *Amphastar*, the plaintiff alleged that the defendants "wrongfully acquir[ed] monopoly power by deceiving the USP into adopting a standard which they later claimed was covered by defendants' patents." *Id.*, 297 F. Supp. 3d at 227.

Contrary to Provepharm's contention, the vague and ambiguous Patented Method Statement buried within its approximately one hundred fifty-one (151)-page submission to USP, dated June 30, 2014, does not conclusively establish that it "actively disclosed" its patent rights to the USP during the revision process, so as to directly contradict Akorn's claim of anticompetitive conduct or render it implausible. (Plaintiff's Memorandum of Law in Support of Motion to Dismiss Counterclaims ["Plf. Mem."] at 14). At best, the Patented Method Statement may affect the weight and credibility of Akorn's counterclaims, but the factual allegations both in the original counterclaims, and as amplified by the proposed amended counterclaims, which are presumed true for purposes of this motion, are nonetheless sufficient "to raise a right to relief above the speculative level." *Twombly*, 550 U.S. 544, 127 S. Ct. at 1959; *see generally Hogan v. Fischer*, 738 F.3d 509, 514 (2d Cir. 2013) ("In ruling on a motion pursuant to Fed. R. Civ. P. 12(b)(6), the duty of a court is merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof.") "The issue is not whether a [claimant] will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Walker v. Schult*, 717 F.3d 119, 124 (2d Cir. 2013).

The case *Rambus Inc. v. F.T.C.*, 522 F.3d 456 (D.C. Cir. 2008), cited by Provepharm, is inapposite as, *inter alia*, it did not involve a motion to dismiss at the pleadings stage. Indeed, the court specifically distinguished the *Broadcom* case from the circumstances of that case on the basis that *Broadcom* "simply reversed a grant of dismissal" and, thus, its ruling "that deceit lured the SSO [standard-setting organization] away from non-proprietary technology" could not help the Federal Trade Commission ("FTC") in *Rambus* because the FTC was unable to find, after

"lengthy proceedings," that the alleged monopolist's behavior caused the SSO's choice.[15] *Id.* at 466. In other words, *Rambus* involved a failure of proof, not a failure of pleading.

The cases Provepharm cites that were decided at the pleadings stage, *ChriMar Sys., Inc. v. Cisco Sys., Inc.*, 72 F. Supp. 3d 1012 (N.D. Cal. 2014); *Apple Inc. v. Samsung Elecs. Co., Ltd.*, No. 11-cv-1846, 2011 WL 4948567 (N.D. Cal. Oct. 18, 2011); and *Townshend v. Rockwell Int'l Corp.*, No. C99-0400SBA, 2000 WL 433505 (N.D. Cal. Mar. 28, 2000), are distinguishable. *Apple* involved the development of technical industry standards in the wireless communications industry and, specifically, the SSOs development of a UMTS standard, designed to support increased speeds and bandwidth capacity on mobile devices, which ultimately incorporated the defendants' patented technology that the defendants had failed to disclose to the SSOs. *Id.*, 2011 WL 4948567, * 1-2. There is no indication in that case that there was a pre-existing UMTS standard that had already been adopted by the SSOs which the defendants merely sought to revise. The district court, relying upon *Rambus*, 522 F.3d 456, held that a pleader alleging anticompetitive conduct based on a theory of failure to disclose intellectual property rights ("IPR") to an SSO during a standard-setting process, "must allege that there was an alternative technology that the SSO was considering during the standard setting process and that the SSO would have adopted an alternative standard had it known of the patent holder's intellectual property rights." *Apple*, 2011 WL 4948567, at *5. The court further held that, without more, such as "factual allegations that there were other technologies considered by the SSO at the time of standard setting," Apple's conclusory allegations that "[h]ad Samsung properly disclosed the existence of its IPR, the relevant SSO would have selected a viable alternative technology or

[15] *Rambus* alternatively held that to the extent that *Broadcom*'s ruling "may have rested on a supposition that there is a cognizable violation of the Sherman Act when a lawful monopolist's deceit has the effect of raising prices (without an effect on competitive structure), it conflicts with *NYNEX* [*Corp. v. Discon, Inc.*, 525 U.S. 128, 119 S. Ct. 493, 142 L. Ed. 2d 510 (1998)]." at 466. However, that holding is not relevant to this case.

would have decided not to incorporate that proposal into the standard[,]" were insufficient to state a plausible claim for monopolization under Section 2 of the Sherman Act. *Id.* at * 6.

Similarly, the anticompetitive conduct alleged in *Townshend* involved, *inter alia*, the counterclaim-defendants' conduct during the standards-setting process before the International Telecommunications Union ("ITU"). Specifically, the counterclaims alleged, *inter alia*, that the counterclaim-defendants lobbied the ITU to adopt an industry standard for the operation of 56K PCM modem chipset products incorporating their patented technology (the "V.90 standard") without disclosing that they had filed a trade secret action in state court against the counterclaim-plaintiff, or that they intended to file a patent infringement suit against the counterclaim-plaintiff. *Id.*, 2000 WL 433505, at * 1-2, 11. Like *Apple*, there is no indication in *Townshend* that there was a pre-existing V.90 standard that had already been adopted by the SSO which the defendants merely sought to revise or amend. Moreover, the district court in *Townshend* merely distinguished the case upon which the counterclaim-plaintiff relied, *i.e.*, an FTC case finding anticompetitive conduct based upon a firm's lobbying for an industry standard incorporating its patented technology without disclosing its patent rights to the SSO during the process, from the case before it on the basis that, unlike the FTC case, the counterclaim-defendants' patents issued only after the ITU had adopted the V.90 standard; the counterclaim-defendants had informed the ITU about their pending patent applications covering the 56K chipset modem technology; and the counterclaims did not assert that the ITU "could have adopted a V.90 standard which did not encompass [their] technology," whereas in the FTC case, "the standards-setting body was choosing among options, and there was a possibility that they could have adopted a standard which did not incorporate [the firm's] patents." *Id.*, at * 11.

In contrast to *Apple* and *Townshend*, this case involves the revision to an existing official monograph in the USP-NF that was initiated by Provepharm, not the development of a new standard or monograph; and there is no indication that the USP would have revised the existing monograph for methylene blue but for Provepharm's request therefor. In other words, assuming the truth of the factual allegations in the counterclaims and proposed amended counterclaims, the USP had already adopted an official standard for methylene blue in the USP-NF which Provepharm sought to revise, purportedly without disclosing its patent rights on the manufacturing processes allegedly necessary to comply with the revised monograph it requested. Drawing all reasonable inferences in favor of Akorn as required on this motion, since there was an existing official monograph for methylene blue in the USP-NF, it may reasonably be inferred that had Provepharm disclosed its patent rights to USP, USP would not have revised the methylene blue monograph at all, much less as requested by Provepharm. Thus, even assuming, *arguendo*, that a party asserting a claim under Section 2 of the Sherman Act based upon a failure to disclose intellectual property rights to an SSO must plead that an alternative standard or technology which did not incorporate the defendant's intellectual property rights was available in order to withstand dismissal at the pleadings stage, Akorn's counterclaims plausibly state such a claim.[16]

[16] The Court is not necessarily persuaded that this is a proper pleading standard, as opposed to an evidentiary standard. *Apple* relies on *Rambus* to hold that the pleader "must allege that there was an alternative technology that the SSO was considering during the standard setting process and that the SSO would have adopted an alternative standard had it known of the patent holder's intellectual property rights." *Apple*, 2011 WL 4948567, at *5. However, as set forth above, *Rambus* involved a failure of proof, not a failure of pleading. Moreover, *Townshend* did not set forth a pleading standard at all with respect to claims alleging anticompetitive conduct based upon alleged misconduct before an SSO; it merely distinguished two (2) cases based upon their facts. However, since Akorn's counterclaims allege sufficient facts suggesting the possibility that USP would not have revised the existing official monograph for methylene blue as requested by Provepharm had Provepharm disclosed its patent rights during the revision process, it is unnecessary to decide this issue.

Although *ChriMar* similarly involved amendments to an existing industry standard, that case is nonetheless also distinguishable from this case. In that case, the counterclaims alleged, *inter alia*, that the counterclaim-defendant, as a participant in the standards-setting process, was required, but failed, to disclose to the SSO, *i.e.*, the Institute of Electrical and Electronics Engineers ("IEEE"), its belief that its patent was essential to the proposed amendments to the existing industry standard for Power over Ethernet-enabled products. *ChriMar*, 72 F. Supp.3d at 1015-1016. There is no indication in that case as to who sponsored the amendments ultimately adopted by the IEEE; only that the counterclaim-defendant was a participant in the standards-setting process and, as such, had a duty to disclose any patents it "believed to be infringed by the practice of the proposed standard" pursuant to the IEEE's "patent disclosure policy." *Id.*, at 1015. In addition, there is no indication in that case as to the counterclaim-defendant's market share in the relevant market. Accordingly, the district court found, in relevant part, that the counterclaims failed "to sufficiently allege market power," *i.e.*, that the counterclaim-defendant had acquired sufficient monopoly power, because they did not "clearly allege that the IEEE would have adopted an alternative standard had it known about" the counterclaim-defendant's patent or position with respect to its patent. 72 F. Supp. 3d at 1019.

Unlike *ChriMar*, the counterclaims in this case contain sufficient factual allegations from which it may reasonably be inferred that Provepharm acquired sufficient monopoly power in the relevant market based upon, *inter alia*, (i) its solicitation of the USP to revise the pre-existing official monograph to include a different hydrate form of methylene blue that purportedly results from Provepharm's patented manufacturing process, without disclosing its patent rights to the USP, plausibly suggesting that the USP would not have revised the existing monograph for methylene blue as requested by Provepharm had Provepharm disclosed its patent rights; (ii) the

barriers to entry or re-entry into the relevant market as a result of USP's adoption of the revised monograph requested by Provepharm; and (iii) Provepharm's substantial market share in the relevant market following USP's adoption of the revised monograph it requested. *See, e.g. Actividentity Corp. v. Intercede Grp. PLC*, No. C 08-4577, 2009 WL 8674284, at * 4 (N.D. Cal. Sept. 11, 2009) (finding that allegations that the alleged monopolist had approximately ninety percent (90%) of the relevant market and failed to disclose its intellectual property rights to the SSO before the standards it adopted had "garnered significant market acceptance;" that the SSO "would have changed the recently-adopted standard but for [the alleged monopolist's] failure to disclose"; and that as a result of the alleged monopolist's failure to disclose, it "obtained a monopoly market share as the market became 'locked in' to the standard," were sufficient to state a monopolization claim under Section 2 of the Sherman Act). Indeed, the USP Submissions Guideline reveals the importance of intellectual property rights in the standards-setting process, (*see* Grant Decl. 4 at 1-2, 4), and, contrary to Provepharm's contention, can be read to apply to patents on manufacturing processes, as well as on testing and assaying methods and procedures.[17] Accordingly, the counterclaims and proposed amended counterclaims contain sufficient factual allegations to state a plausible claim that Provepharm engaged in anticompetitive conduct by soliciting the USP to revise the official monograph for methylene

[17] The Submissions Guideline provides, in pertinent part, that "because USP's standards are intended to be public standards available for the use and benefit of all parties, USP requests that sponsors disclose in their Requests for Revision whether *any portion* of the methods or procedures submitted is subject to patent or other sponsor-held intellectual property rights. In cases where patented methods, procedures or materials required for compendial tests and assays (such as RS or photomicrographs) are proposed, USP may seek assistance from the sponsor in in obtaining clearance or license for use by any persons seeking to use or apply a USP public standard incorporating such method, procedure or material, and may consider other approaches including the solicitation of other Requests for Revision that use alternative methods or procedures. USP reserves the right to indicate in a resulting monograph or general chapter whether methods or procedures are subject to such intellectual property rights." For purposes of this motion, all reasonable inferences must be construed in favor of the non-moving party, and it may reasonably be inferred from that entire provision that sponsors, such as Provepharm, are required to disclose their patents on "any portion of the methods or procedures submitted," including manufacturing processes, to the USP in their Requests for Revision.

blue without disclosing its patent rights with respect to the manufacturing process necessary to produce the methylene blue in the hydrate form incorporated in the revised standard; and that USP would not have revised its official monograph for methylene blue but for Provepharm's alleged conduct.

ii. Antitrust Injury

The Second Circuit has "established a three-part test for determining whether the plaintiff has alleged an antitrust injury: (1) the court must identify the practice complained of and the reasons such a practice is or might be anticompetitive, . . . (2) the court must identify the actual injury the plaintiff alleges [] which requires [it] to look to the ways in which the plaintiff claims it is in a worse position as a consequence of the defendant's conduct, . . . and (3) the court compares the anticompetitive effect of the specific practice at issue to the actual injury the plaintiff alleges. . . ." *IQ Dental*, 924 F.3d at 62-63 (quotations, alterations and citations omitted).

Akorn has sufficiently alleged that Provepharm's anticompetitive conduct, *i.e.*, its alleged misrepresentations to the USP during the standards-revision process, affected the methylene blue market in the United States, and that Akorn's sales of its methylene blue product suffered as a result, sufficient to state a plausible claim of actual antitrust injury.[18] *See, e.g. IQ Dental*, 924

[18] In asserting that the counterclaims fails to state a plausible claim of antitrust injury, and is barred by the *Noerr-Pennington* doctrine, Provepharm focuses upon its "right to obtain NDA approval for ProvayBlue®, and with it Orphan Drug Exclusivity[,]" (Plf. Mem. at 18), seemingly ignoring that the anticompetitive conduct alleged is Provepharm's purported deception in sponsoring the revised methylene blue standard before the USP without disclosing its patent applications directed to the revised standard, which, in combination with the FDA approval of its NDA, operated to reduce consumer choice, significantly heighten barriers to entry, and substantially foreclose competition in the methylene blue market in the United States. Provepharm's petitioning of the USP, a private standards-setting organization, for a revised methylene blue standard "generally does not trigger *Noerr-Pennington* protection." *Amphastar Pharm. Inc. v. Momenta Pharm., Inc.*, 850 F.3d 52, 56 (1st Cir. 2017) (citing *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 500, 108 S. Ct. 1931, 100 L. Ed. 2d 497 (1988)); *see also Hospital Auth. of. Metro. Gov't of Nashville v. Momenta Pharm., Inc.*, No. 3:15-1100, 2016 WL 5724306, at * 15-16 (M.D. Tenn. Sept. 29, 2016), *report and recommendation adopted in relevant part and rejected on other grounds*, 244 F. Supp. 3d 705, 715-16 (M.D. Tenn. Mar. 21, 2017) (finding that since the crux of the plaintiff's antitrust claim

F.3d at 63-64 (finding that allegations that the defendants' anticompetitive conduct affected the market, and that the plaintiff's sales suffered as a result, "is the type of injury the antitrust laws were designed to prevent" because the plaintiff "is entitled to conduct its business in a market that is not infected with an anticompetitive distortion.") Moreover, assuming the truth of Akorn's allegations, *inter alia*, that Provepharm's alleged anticompetitive conduct effectively prevents or delays any other drug manufacturer's entry or re-entry into the market because they cannot seek an NDA to market any product having methylene blue API in accordance with USP's revised monograph without producing the API in accordance with Provepharm's patented manufacturing processes and, thus, without infringing upon Provepharm's patent rights, such conduct "does not simply harm a competitor or two, but threatens to reduce competition in the [methylene blue] market, . . . [and] is precisely the type that the antitrust laws were designed to protect against."[19]

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was the defendants' alleged misconduct before the USP, a private standards-setting organization, the *Noerr-Pennington* doctrine was inapplicable).

Provepharm also apparently ignores the fact that the FDA's award of ODE to ProvayBlue® is for the treatment of pediatric and adult patients with acquired methemoglobinemia only; it allegedly does not prevent Akorn and others from submitting their own NDA for approval to market products having methylene blue API for any other indication or use, or from manufacturing and selling any such product under an approved NDA. Assuming the truth of the allegations in the counterclaims, it is Provepharm's alleged anticompetitive conduct, not the limited ODE protection, which restricts Akorn and other drug manufacturers from manufacturing and selling products with methylene blue API in the United States under their own NDA for any other use than that covered by the ODE, because the manufacturing process purportedly necessary to produce methylene blue in the form adopted by the USP in the revised monograph is allegedly covered by Provepharm's patents. Moreover, since the counterclaims plausibly allege that Akorn and other drug manufacturers would be subject to suits for patent infringement for their marketing of methylene blue, not merely the submission of their own NDAs for FDA approval, the safe harbor provision of the Patent Act, 35 U.S.C. § 271(e)(1), is not applicable.

[19] Provepharm's contentions regarding the merits of Akorn's patent allegations are improper on a motion to dismiss at the pleadings stage. Since Rule 8(a)(2) of the Federal Rules of Civil Procedure only requires a pleading to contain "a short and plain statement of the claim showing that the pleader is entitled to relief," Akorn's counterclaims need not provide further "analysis," "explanation" or "more of a factual basis;" nor conclusive or "self-evident" proof of any fact. (Plf. Mem. at 23). While Provepharm contends that its patents protect only "one method for purifying methylene blue, [and that] it is not self-evident that this is the only method[,]" (Plf. Mem. at 23) (emphasis omitted), "there remain fact-intensive questions about the feasibility, availability and even existence of [any] alternative[] [methods]." *Amphastar*, 297 F. Supp. 3d at 229. "The existence of alternatives is a factual question inappropriate for resolution on a motion to dismiss." *Id.*; *see, e.g. In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 101 (2d Cir. 2017) (rejecting the defendant's argument that the plaintiff's causation theory was implausible because it failed "to rule out a litany of alternative possible causes of [the plaintiff's] delayed market entry," because "[w]hile it [was] possible that one or more of th[o]se factors may turn out to be barriers to plaintiff's causation theory at later stages

Actavis, 787 F.3d at 661 (quotations and citation omitted); *see, e.g. U.S. ex rel. Krahling v. Merck & Co., Inc.*, 44 F. Supp. 3d 581, 599 (E.D. Pa. 2014) ("Plaintiffs have successfully pled a claim for a § 2 violation. Taking the facts in the light most favorable to Plaintiffs, Defendant's fraudulent misrepresentations about Defendant's own product, coupled with the unique facts of this case (e.g., the 100% monopoly of the market and the arguable statutory and contractual duties to disclose information) create the basis for an antitrust claim that Defendant willfully maintained monopoly power through exclusionary tactics. Plaintiffs have argued sufficient facts to sustain a claim for proximate causation, detailing the significant barriers that other companies would face to enter the Mumps vaccine market.")

"An antitrust plaintiff must show that a defendant's anticompetitive act was a 'material' and 'but-for' cause of plaintiff's injury, although not necessarily the sole cause." *Actos*, 848 F.3d at 97. "Further, 'a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury.'" *Id.* at 97-98 (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n. 9, 89 S. Ct. 1562, 23 L. Ed. 2d 129 (1969)); *see also In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012) ("[A]n antitrust defendant's unlawful conduct need not be the *sole* cause of the plaintiffs' alleged injuries; to prove a 'causal connection' between the defendant's unlawful conduct and the plaintiff's injury, the plaintiff need only demonstrate that the defendant's conduct was a substantial or materially contributing factor in producing that injury. (quotations, alterations and citation omitted)). "[C]ausation questions are peculiarly within the competence of the factfinder and should be left for the jury." *Amphastar*, 297 F. Supp. 3d at 228 (quotations and citations omitted); *see also*

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of the litigation, they do not mandate dismissing the complaint [at the pleadings stage]. . . . Dismissal at this early stage on the basis of speculation about possible and not inherently more plausible alternative causes would be premature.")

Taylor Publ'g Co. v. Jostens, Inc., 216 F.3d 465, 485 (5th Cir. 2000) "[T]he question of causation is generally a factual question for the jury. . . ."); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *13 (D. Mass. Jan. 25, 2018) ("[C]ausation is generally a question best left for the jury to decide."); *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) ("The presence of the requisite causation is normally a question of fact for a jury[.]" (quotations, alterations and citation omitted)).

Akorn's allegations that Provepharm's purportedly deceptive conduct during the standards-setting process before the USP led to the revision of the official methylene blue monograph and the subsequent exclusion of Akorn from the relevant market, at least for the period from October 2016 until June 2017, and from when Akorn's remaining product sells out; and that Akorn cannot seek an NDA to market any product having methylene blue API in accordance with USP's revised standards without producing the API in accordance with Provepharm's patented manufacturing processes and, thus, without infringing upon Provepharm's patent rights, are sufficient to state a plausible claim that Provepharm's conduct before the USP was a material cause of the antitrust injury. *See, e.g. Amphastar*, 297 F. Supp. 3d at 228 (finding that the plaintiff's allegations that the defendant's deceptive conduct in front of the USP led to the approval of the [patented standard] and the subsequent exclusion of [the plaintiff] from the marketplace[;] [and that] [t]he adoption of the [patented standard] by the USP made the FDA's approval of the sale of enoxaparin by [the plaintiff] conditional on its use of an infringing procedure[,] . . . adequately pled that the defendants' conduct at the USP was a material cause of the antitrust injury.") Accordingly, Akorn's proposed amended counterclaims are not futile and Provepharm's motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure ism thus, denied in its entirety.

C. Prejudice

The Second Circuit has "referred to the prejudice to the opposing party resulting from a proposed amendment as among the most important reasons to deny leave to amend." *AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 725 (2d Cir. 2010) (quotations and citation omitted); *see also Pasternack v. Shrader*, 863 F.3d 162, 174 (2d Cir. 2017) ("The rule in this Circuit has been to allow a party to amend its pleadings in the absence of a showing by the nonmovant of prejudice or bad faith." (quotations and citation omitted)). "Amendment may be prejudicial when, among other things, it would require the opponent to expend significant additional resources to conduct discovery and prepare for trial[;] . . . significantly delay the resolution of the dispute[,]" *AEP Energy*, 626 F.3d at 725-26 (quotations and citation omitted); *accord City of New York v. Group Health Inc.*, 649 F.3d 151, 158 (2d Cir. 2011), or "prevent the plaintiff from bringing a timely action in another jurisdiction." *Pasternack*, 863 F.3d at 174. "[M]ere delay, [] absent a showing of bad faith or undue prejudice, does not provide a basis for a district court to deny the right to amend[;] . . . [n]or can complaints of the time, effort and money [] expended in litigating the matter, without more, constitute prejudice sufficient to warrant denial of leave to amend." *Id.* (quotations, alterations and citations omitted).

Since the proposed amendments merely assert additional facts in support of Akorn's original counterclaims; do not require additional fact discovery; and will not significantly delay the resolution of this action, Provepharm will not be prejudiced by them. Indeed, although Provepharm indicates that fact discovery is now closed and that amendments in response to a dispositive motion are disfavored, it does not indicate that it needs any additional fact discovery as a result of the amendments; a "second motion to dismiss" will not be required since the Court

has considered Provepharm's motion to dismiss as if it was directed to the proposed amended counterclaims; and neither party has yet moved for summary judgment.[20] Accordingly, Akorn's motion to amend its counterclaims is granted and the proposed amended counterclaims are accepted for filing *nunc pro tunc*.

IV. Conclusion

For the reasons set forth above, Provepharm's motion to dismiss Akorn's counterclaims against it pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure is denied in its entirety; Akorn's motion to amend its counterclaims pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure is granted; and Akorn's proposed amended counterclaims are accepted for filing *nunc pro* tunc.

SO ORDERED.

/s/
Sandra J. Feuerstein
United States District Judge

Dated: June 11, 2019
Central Islip, New York

[20] Even assuming, *arguendo*, that Akorn must establish "good cause" pursuant to Rule 16(b)(4) of the Federal Rules of Civil Procedure to amend its counterclaims after the deadline set forth in the parties' joint letter to the Court setting forth their negotiated discovery schedule, (DE 32), Akorn satisfied that standard by, *inter alia*, asserting its counterclaims by the deadline set forth in the parties' negotiated discovery schedule based upon the evidence before it at that time and then diligently seeking relevant discovery and moving to amend its counterclaims within a reasonable time after receiving the discovery sought. *See generally Holmes v. Grubman*, 568 F.3d 329, 335 (2d Cir. 2009) ("Whether good cause exists [under Fed. R. Civ. P. 16(b)] turns on the diligence of the moving party." (quotations and citation omitted)). Moreover, as set forth above, Provepharm will not suffer any significant prejudice as a result of the proposed amendment. *See generally Kassner v. 2nd Ave. Delicatessen Inc.*, 496 F.3d 229, 244 (2d Cir. 2007) (holding that although "the primary consideration" for purposes of Fed. R. Civ. P. 16(b) "is whether the moving party can demonstrate diligence[,]" the district court may also "consider other relevant factors including . . . whether allowing the amendment of the pleading . . . will prejudice defendants.")